



Exhibit 21

		
HEALTH CARE COMPLIANCE BUSINESS RULES		
Title: Sales Representative's Interactions with Health Care Professionals & Patients	Document # Actavis-BR-01	Version # 2010-01
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1.0 Purpose

- 1.1. The purpose of these Business Rules is to provide a system and instruction, and to assign responsibility for Sales Representative's promotional activities and their interactions with healthcare professionals (HCPs) and patients.

2.0 Scope

- 2.1 It is the policy of inVentiv Health that business is conducted in a manner consistent with the legal, regulatory and ethical standards as contained herein ("Business Rules"), and that all employees shall seek to avoid even the appearance of improper behavior. All sales representatives promoting on behalf of Actavis will be made aware of the legal and regulatory requirements applicable to the operations for which they are responsible and will be accountable for complying with these requirements at all times.
- 2.2 These business rules apply to all inVentiv sales representatives and Field Managers (collectively sales representatives) that interact directly or indirectly with Actavis customers.

3.0 Responsibilities

- 3.1 The inVentiv Health Commercial Compliance Department is responsible for the effective implementation and training of these business rules; and,
- 3.2 Sales representatives are responsible to read, understand and fully comply with the business rules and policies of this program; report to their management any uncertainty concerning any term, statement or part of said business rules.; and,
- 3.3 Actavis is responsible to provide clear direction to inVentiv Commercial Compliance all business rules and policies as required contractually that permit inVentiv Commercial Compliance to develop and implement a healthcare compliance program that meets Actavis's expectations.

4.0 Related Procedures

- 4.1 inVentiv Business Code of Conduct and Ethics
- 4.2 inVentiv Commercial Compliance Handbook
- 4.3 inVentiv Healthcare Compliance Policy

5.0 Related Forms

- 5.1 Commercial Compliance Training Certification Form
- 5.2 Employment Agreement (inVentiv employees only)

6.0 Interactions with Patients

Policy Guidelines on Interactions with Patients

- 6.1 FDA regulations provide that promotional contact with patients or patient support groups constitute direct-to-consumer promotion.
- 6.2 inVentiv clients will determine if inVentiv sales representatives can have direct contact with patients or patient support groups. Therefore, unless client business rules allow, inVentiv sales representatives must not:
 - 6.2.1 Have direct contact with patients and/or patient support groups;
 - 6.2.2 Engage in product discussions with patients and/or patient support groups;
 - 6.2.3 Disseminate promotional or educational materials to patients or patient support groups;
 - 6.2.4 Engage in promotional or educational activities with patients or patient support groups.

Question for Actavis:

- 6.3 Are there additional business rules specific to interactions with patients or patient support groups that need to be communicated to inVentiv sales representatives?

7.0 Use of Educational and Promotional Materials

Policy Guidelines & Business Rules for Sales Representative's Activities

The following sales and promotional activities require client specific business rules to ensure inVentiv sales representatives are trained appropriately and activities are conducted in accordance with state and federal regulations and industry guidelines, inVentiv's Business Conduct Policy, inVentiv's Healthcare Compliance Policy, and the client's policies and procedures.

Educational & Promotional Materials:

The following are inVentiv's policy guidelines for use of Actavis's educational and promotional materials.

- 7.1 inVentiv sales representatives may only use promotional materials that have been approved and provided for use by our Client.
- 7.2 Sales representatives must use Actavis approved promotional and educational materials for their intended use and must always comply with Actavis restriction codes for all promotional and educational material.
- 7.3 Sales representatives must not create or use “homemade” promotional materials including any type of handwritten or printed materials addressing claims, benefits, or uses of a client’s products or comparison to competitive products. Any Actavis unapproved material, such as web site pulls, journal ad copies, reprints, competitor product comparisons and sales aids are not permitted.
- 7.4 inVentiv sales representatives may not make any enhancements or changes to Actavis approved sales aids, including highlighting, underlining and/or any marks such as an asterisk.
- 7.5 Sales representatives may not promote uses of Actavis’s product that are not consistent with the approved product labeling. Sales Representatives must always make statements to healthcare professionals that are within the approved prescribing information and shall always leave a package insert (PI) with each call.
- 7.6 Sales representatives must always ensure product information presented provides a fair balance between the safety and efficacy of the product.
- 7.7 If a Sales Representative receives a request from a physician, pharmacist, or other healthcare professional for off-label information, the Sales Representative must:
 - 7.7.1 Advise the requestor that the product is not approved for the intended use;
 - 7.7.2 Inform the requestor that they are not permitted to engage in off-label discussions or inquiries; and,
 - 7.7.3 Follow Actavis’s business rules for Off-Label Inquiries.
- 7.8 Sales representatives must always be mindful that call notes could be subject to subpoena and therefore, should be written with care and consideration as to their intent and content.

Question for Actavis:

- 7.9 Are there additional business rules specific to the promotion of Actavis products and the use of Actavis's educational and promotional materials that need to be communicated to inVentiv sales representatives?

8.0 Off-Label Inquiries

8.1 inVentiv sales representatives may not:

- 8.1.1 Initiate, prompt, or engage in off-label product discussions;
- 8.1.2 Promote an unapproved product use or indication;
- 8.1.3 Directly or indirectly, solicit "off-label" questions from health care professionals.

8.2 inVentiv sales representatives must respond to unsolicited requests for off-label information in the following manner:

- 8.2.1 Advise the health care professional that you are only permitted to discuss FDA approved uses and/or indications; then follow Actavis business rules for "Off-Label Inquiries."
- 8.2.2 Questions relating to investigational drugs or off-label uses of marketed products must be referred back to Actavis.

Question for Actavis:

- 8.3 How do inVentiv sales representatives respond to unsolicited requests for off-label information by a health care professional?
- Sales representatives are to refer all questions regarding Off-Label inquiries to Actavis Medical Affairs at:
 - **1-888-496-3082**

9.0 Promotional Speaker Programs

9.1 inVentiv sales representatives are not permitted to conduct Promotional Speaker Programs unless our clients determine they have a legitimate business need and gives them permission to do so.

Questions for Actavis:

- 9.2 Will inVentiv sales representatives be permitted to conduct Promotional Speaker Programs? **NO**

If so, does Actavis have:

- 9.2.1 A speaker agreement in place that reflects FMV for the speaker payment?
- 9.2.2 An approved speaker list?
- 9.2.3 Minimum and maximum guidelines set for # of meetings and attendees?

If not:

- 9.2.4 Who would inVentiv sales representatives refer a health care professional to in the event they receive an unsolicited inquiry regarding a promotional speaker program?

At this time Actavis will not be participating in any Promotional Speaker Programs

10.0 Medical Conferences and Conventions

- 10.1 Because commercial activity is perceived as being promotional, attendance and/or participation at medical conferences and conventions must adhere to client specific business rules.
- 10.2 inVentiv sales representative's role, activities, and information used at medical conferences and/or conventions must clearly be defined prior to attendance.

Questions for Actavis:

- 10.3 Will inVentiv sales representatives be allowed to attend and/or participate in medical conferences or conventions?
- 10.4 What business rules apply to sales representatives' actions in booths and/or exhibits?

11.0 Consulting and Service Arrangements

- 11.1 Unless agreed upon in advance and clear direction provided by **Actavis**, inVentiv sales representatives shall play no role in such consulting or service arrangements.
- 11.2 inVentiv employees shall not independently retain or use any health care professional or other individual as consultants. inVentiv sales representatives shall not make any payment directly to a health care professional for such services.

Question for Actavis:

- 11.3 Will inVentiv representatives be engaging in any activities that are related to consulting or service arrangements?

12.0 Educational Grants

- 12.1 inVentiv does not permit sales representatives to have any involvement or decision-making ability in the grant request process. However, we do allow them to disseminate general program information on a client's behalf.

Question for Actavis:

- 12.2 How does Actavis want inVentiv sales representatives to respond when they receive an unsolicited request for an educational grant?

At this time Actavis will not be offering any Educational Grants

13.0 Educational and Medically Relevant Items

- 13.1 inVentiv's Policy **prohibits** sales representatives from providing gifts or non-educational items to a Health Care Practitioner and/or their staff.

- 13.2 If client business rules allow, inVentiv field sales representatives may provide HCPs educational and/or medically relevant items as long as the item:

- 13.2.1 Has been approved by Actavis;
- 13.2.2 Is provided on an occasional basis;
- 13.2.3 Serves a genuine educational and/or clinical need (e.g. textbook);
- 13.2.4 Benefits patients or patient care (e.g. anatomical model);
- 13.2.5 Does not exceed \$100 per industry standard (e.g. textbook)
- 13.2.6 Is not in the form of cash or other cash equivalent where a HCP could purchase an item on his/her own;

Question for Actavis:

- 13.3 Considering inVentiv's policy, state requirements, and the standards set forth in the updated guidance document (CODE) regarding interactions with health care professionals does Actavis have additional business rules that apply to sales representatives providing anything of value to HCPs?
- 13.4 Will inVentiv sales representatives be permitted to distribute non-educational items (i.e. pens, pads, etc.) to HCPs?

- 13.5 Will sales representatives be deployed in states that require adherence to the new updated Code on interactions with health care professionals by state law?

States requiring compliance by State Law:

- California
- Massachusetts
- Nevada

14.0 Meals and Entertainment

- 14.1 inVentiv's policy does not allow sales representatives to provide social activities or hospitality to client customers unless our client's business rules allow.
- 14.2 inVentiv sales representatives may only provide occasional modest meals to client customers.

Questions for Actavis:

- 14.3 Will inVentiv sales representatives provide meals or food to your customers or just HCPs?
- 14.4 What is your definition of a customer?
- 14.5 What is your definition of a HCP?
- 14.6 What is your definition of modest?
- 14.7 What is your definition of occasional?
- 14.8 Will inVentiv sales representatives provide in-office meals?
If yes:
14.8.1 For HCPs only or customers?
14.8.2 For what purpose?
- 14.9 What is your "per-person" spend limit for in-office meals?
➤ [Breakfast] **\$10**
➤ [Lunch] **\$25**
➤ [Dinner]
➤ [Snack]
- 14.10 Will inVentiv sales representatives provide out of office meals to HCPs?
If yes:
14.10.1 For HCPs only or customers?

14.10.2 For what purpose?

14.10.3 Where can out of office meals occur?

14.11 What is your “per-person” spend limit for out of office meals?

- [Breakfast]
- [Lunch]
- [Dinner]
- [Snack]

15.0 Adverse Events and Product Complaints

15.1 inVentiv does not provide an avenue for its sales representatives to report adverse events or product complaints; therefore, we rely on our client’s to provide the reporting requirements and procedures for adverse events and product complaints.

15.2 To ensure we provide appropriate instructions to our representatives please provide a response to following questions in addition to any other information you feel would be appropriate. We treat this as a high-risk area for our clients and want to make sure we communicate the process effectively.

Questions for Client:

15.3 What process does Actavis expect our sales representatives to follow when reporting Adverse Events?

- **To report or access information, regarding Adverse Events and Product Complaints sales representatives are to call:**

- **1-888-469-3082**

15.4 We understand the FDA holds Actavis accountable for reporting adverse events within a specific timeframe. What is Actavis’s reporting requirements once an inVentiv representative is made aware of an adverse event?

15.5 Is there other information than what is listed below that Actavis requires in the report?

15.5.1 Product name and strength;

15.5.2 Product NDC and Lot #;

15.5.3 Reporters name, (healthcare professional) address, and telephone number;

15.5.4 Description and date of the event;

15.5.5 Gender and age of the person affected by the Adverse Event;

15.5.6 Date of the report to the Sales Representative;

15.5.7 Sales Representative's name and contact information.

16.0 Product Complaints

Questions for Actavis:

16.1 What process does Actavis expect our sales representatives follow when reporting Product Complaints?

- **To report or access information, regarding Adverse Events and Product Complaints sales representatives are to call:**

- **1-888-469-3082**

16.2 What is Actavis's reporting requirements once an inVentiv Sales Representative is made aware of a Product Complaint?

16.3 Is there other information than what is listed below that Actavis requires in the Product Complaint report?

16.3.1 Product name and strength

16.3.2 Product NDC and Lot #

16.3.3 Reporter's name, (health care professional) address and telephone number

16.3.4 Description of the defect

16.3.5 Date of report to the Sales Representative

16.3.6 Sales Representative's name and contact information

17.0 State Legislation

17.1 Based on current state legislation for the following states, inVentiv representatives will adhere to the active state legislation and reporting requirements. The following states have current legislation:

- California
- Colorado
- District of Columbia

- Louisiana
- Maine
- Massachusetts
- Minnesota
- New Hampshire
- Nevada
- West Virginia
- Vermont

Question for Actavis:

17.2 Do Actavis representatives cover any of the states indicated?

17.3 Does Actavis have any representatives or direct managers interacting with HCPs in Washington, DC, which now requires licensure?

18.0 Direct Marketing Expense Reporting

18.1 These business rules will be addressed in the template provided by our Sales Force Automation team.

18.2 These business rules will be applied to the representative's Target Mobile System for use in reporting Direct Marketing Expenses.

19.0 Contact Information and Available Resources

19.1 inVentiv employees have multiple resources available to them if they have compliance questions or concerns (i.e. Compliance Hotline and Website).

19.2 Although we instruct our sales representatives to contact their manager when questions arise, we also inform them that inVentiv's Commercial Compliance Department, Human Resources, and the Compliance Hotline are other available resources.

Question for Actavis:

19.3 In addition to inVentiv's available resources would Actavis want us to include any additional resources for inVentiv sales representatives?

Representatives are to contact their District managers

20.0 Revision History

Change #	Developed by	Reason for Revision	Effective Date
1	Scott Miller	Added new section 17 - State Legislation	01-05-2010

Health Care Compliance Business Rules

By signing and dating this document below, I understand and approve of the information supplied in the Health Care Compliance Business Rules.

 Scott Miller, Director, Corporate Compliance, inVentiv Health (Date)

 (Signature), (Title), Actavis (Date)

 (Signature), (Title), Actavis (Date)